REMARKS

The present invention relates to novel cancer vaccines. More particularly, the invention relates using hapten-modified syngeneic tumor cells to elicit anti-tumor T cell responses in a cancer patient thereby providing a therapeutic benefit. Claims 7 and 8 have been canceled herein solely to expedite prosecution of the present application.

Restrictions/Elections

Applicant acknowledges the further restriction of newly added claims 22-24. Applicant hereby cancels claims 23 and 24 solely to expedite prosecution of the present application.

Rejections

(1) Claims 2, 6-8, and 22 stand rejected under 35 U.S.C. §112, first paragraph for not providing enablement for administering human tumor "substantially" in the phrase "substantially in a no growth state."

(2) Claims 2, 6, 7, and 22 stand rejected under 35 U.S.C. §112, first paragraph, for not providing enablement for administering haptenized syngeneic colon cancer cells with immunological adjuvants other than BCG. Hoover, et al. (1985, Cancer 55:1236-1243) and U.S. Patent No. 5,290,551 to Applicant (the '551 patent) are cited in the Office Action to support this rejection.

(3) Claims 2, 6-8 and 22 stand rejected under 35 U.S.C. §103(a) for being obvious in view of Hoover, et al. and the '551 patent. The Office Action states that Hoover et al. teach treatment of colon carcinoma cells using BCG as an adjuvant, and the '551 patent teaches treatment of melanoma with a haptenized tumor cell vaccine.

(4) Claims 2, 6-8, and 22 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office Action states that the claims are confusing in using the terms "adenocarcinoma" and "colon carcinoma" interchangeably.

(5) Claims 2, 6-8, and 22 stand rejected under 35 U.S.C. §112, first paragraph, as lacking written description. It is stated in the Office Action that the use of an adenocarcinoma cell to treat colon carcinoma is not supported by the specification.

(6) Claims 2, 6-8, and 22 stand rejected under 35 U.S.C. §112, first paragraph, for not providing enablement for treating colon carcinoma with any adenocarcinoma cell.

Responses

With regard to rejection (1), this rejection is rendered moot in view of Applicant's amendment of claim 2 to delete reference to the term "substantially." Applicant requests reconsideration and withdrawal of the rejection.

With regard to rejection (2), this rejection is rendered moot in view of Applicant's amendment of claim 2 to recite that the adjuvant is BCG.

With regard to rejection (3), Applicant respectfully submits that the combination of Hoover et al. and the '551 patent does not render claims 2, and 6-8, as amended, *prima facie* obvious under 35 U.S.C. § 103(a), for the following reasons.

The three-prong test which must be met for a reference or a combination of references to establish a *prima facie* case of obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142.

At least one of these criteria has not been met here.

The Examiner contends that Hoover et al. discloses immunotherapy using irradiated colon cancer cells with BCG, and acknowledges that Hoover et al. does not teach haptenization of the cells. The Examiner also asserts that the '551 patent teaches haptenized melanoma cells, but notes that the '551 patent does not disclose colon carcinoma. Applicant respectfully submits that the combination of these references cannot support a finding of *prima facie* obviousness under 35 U.S.C. §103(a).

As pointed out by the Examiner, Hoover et al. does not teach or suggest use of a hapten in treating colon carcinoma. Also as pointed out by the Examiner, the '551 patent does not teach or suggest treating colon carcinoma. However, there is no disclosure in either reference that would motivate a person of ordinary skill in the art to combine one reference with the other. Nothing in Hoover et al. motivates the reader to combine the Hoover et al. reference with the '551 patent to try haptenizing the tumor cells of the vaccine taught in Hoover et al. to treat colon carcinoma. Likewise, nothing in the '551 patent motivates the reader to combine the '551 patent with the Hoover et al. reference. That is, nothing in the '551 patent would indicate to a person of ordinary skill in the art that the haptentized tumor cell vaccine taught in the '551 patent would be useful in treating colon carcinoma. This prong of the test for *prima facie* obviousness has not been satisfied and the rejection should be reconsidered and withdrawn.

Even if the references were combined, there could be no reasonable expectation of success in combining these references to arrive at the methods of the Applicant's invention. A person of ordinary skill in the art, reading Hoover et al. and the '551 patent, would not reasonably expect to succeed in producing a haptenized tumor cell vaccine to treat colon carcinoma by combining the teachings of Hoover et al. with those of the '551 patent. There is nothing to indicate in either reference, even when

combined, that colon carcinoma could be treated by administering a haptenized tumor cell vaccine. This prong of the test for *prima facie* obviousness has not been satisfied and the rejection should be reconsidered and withdrawn.

For the reasons discussed above, the combination of Hoover et al. with the '551 patent cannot render claims 2, 6-8, and 22, as amended, *prima facie* obvious under 35 U.S.C. § 103(a) and, therefore, the rejection should be reconsidered and withdrawn.

With regard to rejections (4)-(6), these rejections are rendered moot in view of Applicant's amendment of claim 2 to recite "colon carcinoma" throughout the claim. Applicant requests reconsideration and withdrawal of these rejections.

Summary

Applicant respectfully submits that each rejection of the Examiner to the claims of the present application has been either overcome or is now inapplicable, and that each of claims 2, 6, and 22, is in condition for allowance. Reconsideration and allowance of each of these claims are respectfully requested at the earliest possible date.

Respectfully submitted,
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(Date)

By: _____

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Enclosure (Petition for two-month extension of time and associated fee)